

REMARKS

This response is submitted in reply to the Office Action mailed March 5, 2007 ("the Action"). Claims 1-24, 51-53 and 61-65 are pending in the application. A three-month extension of time is being concurrently submitted herewith.

I. The Allowable Subject Matter

Applicant acknowledges with appreciation the Examiner's statement that Claims 12-14 and 17 would be allowable if rewritten in independent form including the limitations of the base claim and any intervening claims. Applicant has amended Claims 12 and 14 to independent form incorporating base Claim 1. Claims 13 and 17 depend directly or indirectly from Claim 12. Accordingly, Applicant respectfully submits that Claims 12-14 and 17 are in condition for allowance, which action is respectfully requested.

II. The Art Rejections

The other claims stand rejected as being anticipated by and/or obvious over U.S. Patent No. 4,472,091 to Callahan ("Callahan"). Applicant respectfully disagrees.

A. The 102(b) Rejections

The Action rejects Claims 1-2, 5, 7-11, 15-16, 18, 21-24, 51-53 and 61-62 as being anticipated by Callahan. The Action alleges that Callahan teaches (1) generating a non-linear vibration input signal comprising a plurality of different selected frequencies that correspond to a dry powder formulation (citing to col. 2, lines 45-68, col. 2, lines 1-64 and col. 4, lines 1-66); (2) that the selected frequencies correspond to flow characteristic frequencies of the dry powder; and (3) that the generating step is carried out to cause the dry powder to flow in a substantially uniform fluidic manner citing to col. 3, lines 27-41. The Action concludes that the device proposed by Callahan "will perform the method recited in Claims 1-3 during normal operational use of the device." Action, p. 3. Applicant respectfully disagrees.

Callahan proposes a dry powder metering apparatus that includes a dry powder supply chamber with a mixing chamber for forming an air-powder mixture. The device includes a tapered plug 34 bonded to an end of a thin, flat cantilevered metallic beam 30 (Abstract, Figure

1, col. 2). Oscillating voltage applied to the beam 30 causes the tapered plug 34 to move up and down to vary the width of the annular gap G in the neck of the powder supply chamber between the tapered plug 34 and the exit neck of the chamber 20 to limit the amount of powder "capable of falling therethrough" (Abstract). The tapered plug 34 includes a rod 54 that penetrates the powder P in the supply chamber 20. Callahan states that the rod can vibrate to help with free flow of powder through an annular gap.

Since dry powder may not fall freely through gap G of its own accord...an oscillating fixed frequency voltage component is impressed upon piezoelectric elements 36 and 38 by a control oscillator to cause the deflected beam 30 to vibrate in accordance with the frequency of oscillations, typically 60 Hz. Vibration of beam 30 cause plug 34 and rod 54 to vibrate therewith to help insure free flow of powder P through gap G into mixing chamber 22."

Col. 3, lines 27-39. Further, Callahan proposes an AC component, typically 60 Hz, from a fixed frequency control oscillator (col. 2, lines 13-14). Notably, this device proposes the use of a single fixed frequency not multiple selected frequencies.

Thus, Applicant agrees that Callahan proposes that the tapered plug may provide some type of vibration to the powder as the beam 30 oscillates to move the plug and rod 54 up or down, but the vibration is non-specific as to the powder or with respect to using a plurality of frequencies. Clearly, Callahan does not describe vibratory frequencies selected to correspond to the dry powder formulation in the hopper, much less frequencies that correspond to flow characteristic frequencies of the dry powder. Further, "free flow" of powder does not necessarily mean "uniform fluidic flow" which can be particularly problematic for dry powder, particularly fluidic flow of very small, dispensed amounts and/or low-density dry powders.

Advantageously, embodiments of the invention provide vibratory input signals that include a carrier signal modulated by selected frequencies to promote improved repeatability and/or fluidization of the dry powder.

Applicant respectfully submits that independent Claims 1, 51 and 52 (and new Claim 66) are patentable over Callahan as Callahan fails to teach or suggest, *inter alia*, that the vibratory signal comprises a carrier signal modulated by a plurality of different selected frequencies.

The noted dependent claims are also not anticipated by Callahan for at least the emphasized features set forth below.

Claim 2 recites that the selected frequencies correspond to flow characteristic frequencies of the first dry powder.

Claim 7 recites that the non-linear input signal has a plurality of superpositioned modulating frequencies.

Claim 18 recites that the applying step is carried out to concurrently apply vibrational energy to the flow path at multiple superimposed selected frequencies.

Applicant respectfully submits that the claims are not anticipated by Callahan and request that these rejections be withdrawn.

B. The Obviousness Rejections

The Action rejects Claims 3-4 and 6 because it has been allegedly held that where the "general conditions" of a claim are disclosed in the prior art, discovering "optimum or workable ranges" involves only routine skill (citing to MPEP 2144.05).

Claims 3-4 and 6 relate to very small meted quantities and/or reliable dispensing. Reliable dispensing of small quantities of dry powder has been problematic. Thus, selecting the signal and the appropriate frequencies to provide the uniform fluidic flow response to aid in metering small quantities (reliably) of dry powder is not merely discovering "optimum or workable ranges".

The cited MPEP section is directed to an overlap of ranges or a variation of certain parameters, such as concentration or temperature. However, embodiments of the invention, instead of using a fixed frequency based on the piezoelectric or oscillator, employ a relatively complex vibratory signal with a carrier frequency modulated with a plurality of selected frequencies. This is clearly different from the situation where, for example, one would use a single frequency of 40 Hz versus the noted 60 Hz proposed by Callahan.

The Action also rejects Claims 19-20, which are directed to frequency ranges because it has been held that where the "general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art" (Action, p. 4), again citing to MPEP 2144.05.

However, the claimed frequencies and the claimed vibratory signal are very different from the vibration proposed by Callahan. Indeed, the only description that Applicant could find with respect to vibration frequencies in Callahan was directed to obtaining a deflection of the beam (col. 4, lines 38-62). For example, Callahan states that by applying a "controlled oscillating voltage of fixed frequency 60 Hz, for example, to the piezoelectric elements 36 and 38 by means of control oscillator 58 as shown in Figure 3, a constant vibration of 60 Hz per second of the deflected beam results....(col. 4, lines 38-42).

Notably, however, the affected claims are not directed to just any modification of vibratory frequency, but rather to frequencies based on the powder being dispensed which promotes more reliable fluidization.

Similarly, the Action rejects Claims 63-65 because, while conceding that Callahan fails to teach the use of three or four superpositioned modulating frequencies, it alleges that it would have been [somehow] obvious to do this "since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art." Action, p. 4 (citing to MPEP 2144.04). Again, Applicant respectfully disagrees.

First, Applicant notes that this section of the MPEP states that if the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection. This MPEP section also states that the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. Further, the claimed systems and methods are not merely duplicating working parts of a device, they are providing novel vibratory signals that promote dry powder fluidization. Applicant submits that the claimed carrier frequency with the modulating frequencies provide improved fluidity of flow for dry powders and the vibratory signal and frequencies do provide new and unexpected results in promoting fluidization of the dry powder.

III. Experimental Data

As discussed by Dr. Crowder (one of the inventors of the pending application) in *Precision powder metering utilizing fundamental powder flow characteristics*, Powder Technology 173 (2007) 217-223, experimental results using vibration frequencies calculated from physical characterization of the dry powders indicated that the vibratory signal with these frequencies "had a significant influence on the reproducibility of metering". (Abstract). See also, Figures 5 and 6 of this article provided hereinbelow for ease of reference, which demonstrate flow filling data comparing sinusoidal to powder specific vibration.

Figure 5

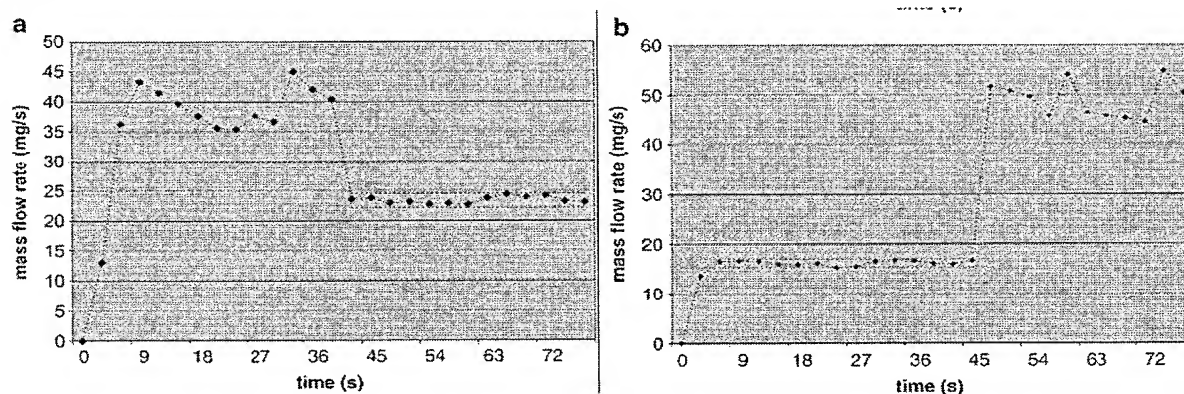
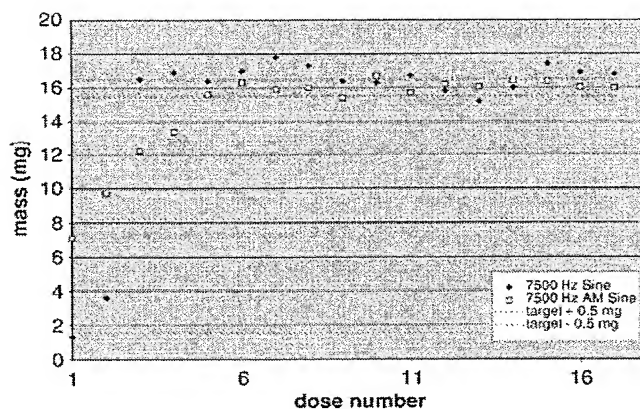


Figure 6



Thus, Applicant respectfully submits that the claimed vibratory signal is non-obvious over prior art vibrations and clearly provides a more uniform fluidic flow, which can improve filling processes/systems.¹

IV. The New Claims

Applicants have added new Claims 66-76 to form a more complete claim set for the application. Applicants respectfully submit that the claims are supported by the specification (*see, e.g.*, pp. 16-18, 33, and 34). Entry and consideration of the new claims is requested.

V. Related Applications

Out of an abundance of caution, Applicant respectfully notes for the record that divisionals of previously identified patent applications (the parent applications are of record and have been considered by the Examiner in prior Information Disclosure Statements) naming at least one co-inventor and being commonly owned, are also pending.

-- US-2005-0126569-A1 (Attorney Docket No. 9336-2DV)

-- US 2005-0267628-A1 (Attorney Docket No. 9336-3DV)

Applicant also notes for the record that Patent Application Publication Number US 2004-0153262 A1, which was considered by the Examiner (as evidenced on the initialed substitute Form PTO 1449), has issued as U.S. Patent No. 6,985,798.

Certain claims in the instant application (Claims 54-60) were canceled to obviate a provisional Terminal Disclaimer rejection rendered by the Examiner in the prosecution of U.S. Patent No. 7,118,010, (10/607,389). This patent was considered by the Examiner as indicated in a Form PTO 892.

¹ See also, T. Crowder and A. Hickey, *Powder specific active dispersion for generation of pharmaceutical aerosols*. *Int. J. Pharm.* **327** 65-72 (2006), a copy of which is attached hereto (discussion of methods and results of fluidization of dry powder for inhalers using powder specific vibratory signals).

In re: Timothy M. Crowder
Application No. 10/606,676
Filed: June 26, 2003
Page 15

CONCLUSION

Applicant respectfully submits that this application is now in condition for allowance, which action is requested. If any extension of time for the accompanying response or submission is required, Applicant requests that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to our Deposit Account No. 50-0220.

Respectfully submitted,



Julie H. Richardson
Registration No. 40,142

Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401
Customer Number 20792

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on August 30, 2007.

Signature:

Rosa Lee Brinson

